

24. (Amended) An anti-inflammatory pharmaceutical formulation comprising in unit dosage form for oral administration about 10 to about 50,000 IU of human IFN-gamma and a pharmaceutically acceptable carrier therefor.

28. (Amended) A pharmaceutical formulation comprising in unit dosage form for oral administration about 10 to about 50,000 IU of human IFN-gamma, a therapeutic agent selected from the group consisting of an antibiotic, an antifungal, an antifibrotic, and a chemotherapeutic agent known for use in cancer therapy or for treatment of immune diseases characterized by hypoactive or hyperactive immune system dysfunction, and a pharmaceutically acceptable carrier therefor.

REMARKS

Applicants have amended claims 24 and 28. Basis for the amendments is found in the specification and in the originally filed claims.

35 U.S.C. § 112

Claims 24-28 have been rejected under 35 U.S.C. § 112, first paragraph for lack of enablement. Particularly, the Examiner contends that the specification lacks enablement for a pharmaceutical composition comprising a low dose of IFN-gamma (IFN- γ) for the treatment of the diseases listed in the claims other than inflammation. To advance the prosecution of this application and without conceding the validity of the examiner's contention, claims 24-27 have been amended to specify anti-inflammatory pharmaceutical formulations in unit dosage form for oral administration, and claim 28 has been amended to delete reference in the preamble to the several treatment indications. Those amendments are believed to be fully responsive to the Examiner's concerns explained in support of the rejection. Reconsideration of the rejection of claims 24-28 under 35 U.S.C. § 112, first paragraph, leading to withdrawal of that rejection is requested.

35 U.S.C. § 103

Claims 24-27 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,019,382 issued to Cummins (the '382 patent). Applicants respectfully traverse and request reconsideration of the rejection.

The '382 patent discloses use of low dose interferon formulations to treat various diseases. The specification and examples of the '382 patent describe use of low doses of IFN-alpha and IFN-beta. Not one of the examples of the '382 patent describes use of low

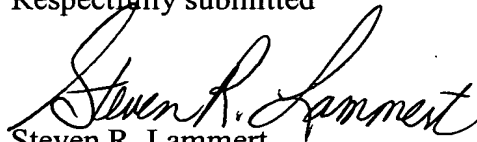
dose formulations of *IFN-gamma*. IFN-alpha and IFN-beta are Type I interferons and are usually acid stable. IFN- γ , a Type II interferon, is acid-labile (captioned application, p. 3, lines 8-10). Respectfully, with fair consideration of the whole of the relevant art, low doses of IFN-gamma for use in oral dosage formulations would not have been obvious to the skilled practitioner at the time the invention was made. The claimed invention cannot be said to have been obvious over the '382 patent description within the meaning of 35 U.S.C. § 103. Withdrawal of that rejection is requested.

Claim 28 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over the '382 patent in view of U.S. Patent No. 6,045,802 issued to Schlom et al. (the '802 patent) or U.S. Patent No. 5,178,857 issued to Goeth et al. (the '857 patent). Applicants respectfully traverse and request withdrawal of that rejection. Claim 28 has been amended to delete reference to the several treatment indications and to specify an oral dosage form.

As discussed above, the '382 patent discloses low dose interferon formulations, but it exemplifies IFN-alpha and IFN-beta compositions only, and it would not have been obvious to substitute acid-labile IFN-gamma in place of acid stable alpha and beta interferon to provide the oral dosage formulations of the present claims; and respectfully, neither the cited '802 patent nor the cited '857 patent overcome the deficiencies of the '382 patent to make the claimed invention obvious under 35 U.S.C. § 103. The '802 patent teaches combination therapy; however, it does not teach or suggest an oral dosage formulation comprising low doses of IFN- γ and another therapeutic agent as specified by rejection claim 28. The '857 patent teaches a combination therapy using IFN- γ and at least one anthelmintic. However, the anthelmintic was administered orally and the IFN- γ was administered parenterally at relatively high doses. Column 7, lines 30-52. As discussed above, it was well known in the art that IFN- γ is acid-labile, and probably not a candidate for oral administration with consequent exposure to acidic digestive conditions. The differences between the cited prior art and the invention specified in claim 28 are such that the invention

as a whole would not have been obvious to a skilled practitioner at the time the invention was made. Reconsideration of claim 28, as amended, leading to withdrawal of the rejection is requested.

Respectfully submitted

A handwritten signature in cursive script, appearing to read "Steven R. Lammert".

Steven R. Lammert

Registration No. 27,653

Attorney for Applicants

SRL:gl
Indianapolis, Indiana 46204
317-231-7258

Appendix to Amendment
Marked-Up Version of Rewritten Claims Under 37 C.F.R. § 1.121(c)(1)(ii)

Application No. 09/672,335

24. [A] An anti-inflammatory pharmaceutical formulation [for treatment of a disease selected from the group consisting of acute inflammation, monocyte, neutrophil, or B cell dysfunction, cancer, bacterial and fungal diseases, and fibrosis, said formulation] comprising in unit dosage form for oral administration about 10 to about 50,000 IU of human IFN-gamma and a pharmaceutically acceptable carrier therefor.

28. A pharmaceutical formulation [for treatment of a disease selected from the group consisting of acute inflammation, monocyte, neutrophil, or B cell dysfunction, cancer, bacterial and fungal diseases, and fibrosis, said formulation] comprising in unit dosage form for oral administration about 10 to about 50,000 IU of human IFN-gamma, a therapeutic agent [selected from the group consisting of an antibiotic, an antifungal, an antifibrotic, and a chemotherapeutic agent known for use in cancer therapy or for treatment of immune diseases characterized by hypoactive or hyperactive immune system dysfunction,] and a pharmaceutically acceptable carrier therefor.